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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT PAPER NUMBER

1632

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

2M
Office Action Summary

Application No.

09/766,154

Applicant(s)

PATIENCE, CLIVE

Examiner

Anne Marie S. Wehbe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,29,31,32,34-41,43-45,47-49,51-55,59 and 60 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 28,29,31,32,34-41,43 and 44 is/are allowed.
6) ☒ Claim(s) 45,47-49,51-55,59 and 60 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/5/03.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response received on 3/3/04 have been entered. Claims 56-58 have been canceled and new claims 59-60 have been added. Claims 28-29, 31-32, 34-41, 43-45, 47-49, 51-55, and 59-60 are pending in the instant application. An action on the merits follows.

Those sections of Title 35, US code not included in this action can be found in the previous office action.

Claim Rejections - 35 USC § 112

The rejections of claims 35-41, and 43-55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of applicant's amendments to the claims.

Claim Rejections - 35 USC § 102

The rejection of previously pending claims 45, 47-49, and 51-58 under 35 U.S.C. 102(b) as being anticipated by Kaeffer et al. is maintained over currently pending claims 45, 47-49, 51-55, and 59-60. Applicant's arguments have been fully considered but have not been found

persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

The applicant has not presented any arguments in response to the grounds of rejection over claims 45, 47-49, and 51-52. Therefore, the rejection of record is maintained over claims 45, 47-49, and 51-52.

In regards to claims 53-55, and new claims 59-60, the applicant argues that the claims are directed to a “transplant” and that organs destined for transplantation are aseptically isolated and stored on ice or in such a way as to maintain their vascular system. The applicant states that Kaeffer et al. does not enable the isolation of organs for transplant and only discloses spleens stored in fluid for mincing. In response, claims 53-55 and 59-60 are directed to a transplant comprising an organ, tissue, or cells from an inbred human tropic PERV free swine. Thus, the claims are not limited to organs which have intact vascular structures. Further, regarding the term “transplant”, it is noted that the use of a product for a particular purpose is not afforded patentable weight in a product claim where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone. The MPEP states that, “.. in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.” *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963)(MPEP 2111.02). The only structural limitations in the instant claims are cells from an inbred human-tropic PERV free swine. As noted in the previous office action, Kaeffer et al. teaches a herd of inbred miniature DD haplotype swine many of which are inherently human PERV-free. Kaeffer et al. also teaches isolated spleens and

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splenocytes from these D/D haplotype swine (Kaeffer et al., page 733). Please note that specifically teaches storing whole spleens aseptically in ELY medium or partially purified splenocytes in sterile medium (Kaeffer et al., page 733). Since the cells are viable and grown aseptically in physiological media, these cells are capable of being transplanted into a host animal. Since the cells recited in the claims as written do not have any structural requirements other than being human tropic PERV free and derived from an inbred swine, Kaeffer et al. meets the claims limitations.

Furthermore, the MPEP states that, when the claimed and prior art products are identical or substantially identical in structure, a *prima facie* case of either anticipation has been established. MPEP 211.01 and In re Best, 195 USPQ 430, 433 (CCPA 1997). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989).

In regards to whether or not the inbred miniature D/D haplotype swine taught by Kaeffer et al. are human trophic PERV free, the previous office action stated that based on the data

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provided in the declaration by Dr. Clive Patience, it is clear that the overwhelming majority of the D/D haplotype swine do not comprise human-tropic PERV. Further, as noted in previous office actions, the applicant states in their specification that the miniature D/D haplotype swine does **not** naturally contain human-tropic PERV (specification, page 18, Table 2, page 28, Table 4). Based on the statements in the specification, and the declaratory data, it is clear that while the population of D/D haplotype swine is mixed in terms of possessing human-tropic PERV, the majority of the D/D haplotype swine are in fact human-tropic PERV negative. Kaeffer et al. teaches miniature D/D haplotype swine from a herd of swine bred since 1985 at Nouzilly (Kaeffer et al., page 732). Thus, contrary to the applicant's arguments, Kaeffer et al. does in fact teach an inbred herd of swine. Further, since Kaeffer et al. teaches a herd of swine, and not just a single swine, the teachings of Kaeffer et al. read on numerous D/D haplotype swine and the use of these swine to isolate spleens and splenocytes. In view of the applicant's own data which shows that the majority of D/D haplotype swine do not have human-tropic PERV, the skilled artisan would recognize that the herd of D/D haplotype swine taught by Kaeffer et al. include swine which are in fact human-tropic PERV negative, and thus both organs and tissues isolated from these swine would likewise be human-tropic PERV negative. Therefore, for reasons of record as discussed in detail above, the rejection of record is maintained.

Allowable Subject Matter

Claims 28-29, 31-32, 34-41, and 43-44 are considered free of the prior art of record and allowable at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

